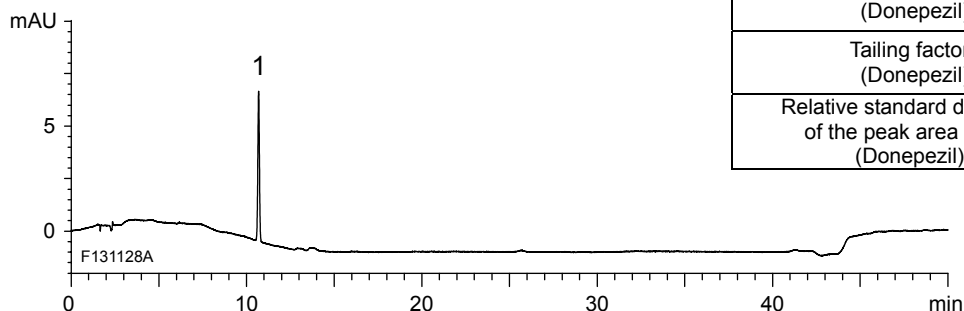


ドネペジル塩酸塩 (米国薬局方記載条件)

Donepezil hydrochloride (The United States Pharmacopeia)

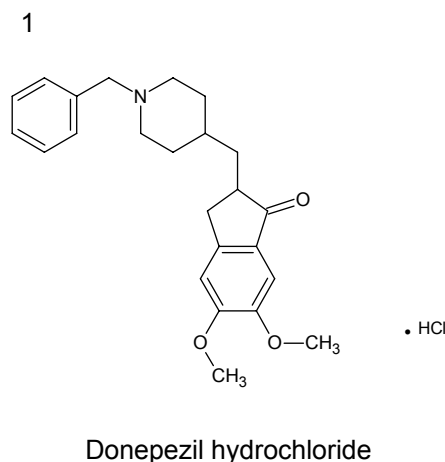
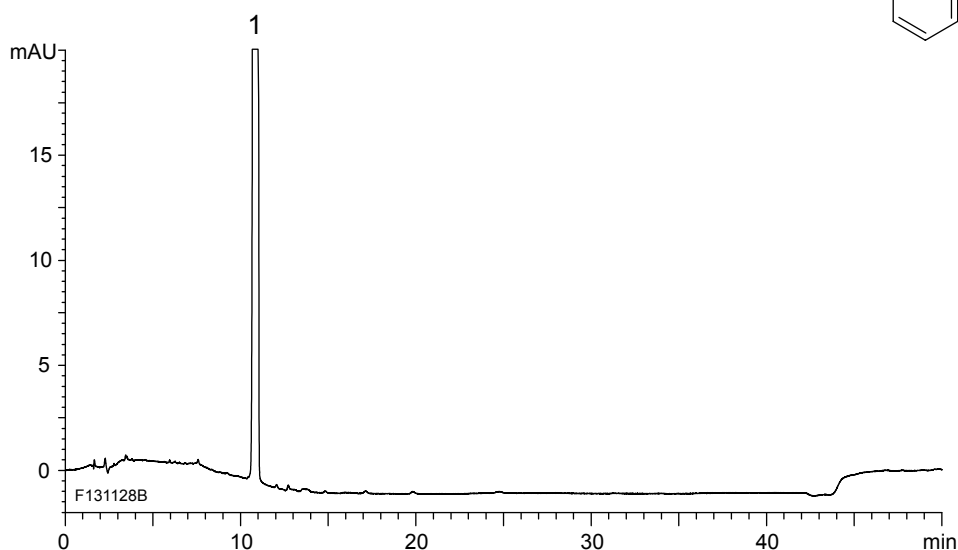
F131216A

(A) Standard solution\*  
(0.01 mg/mL Donepezil hydrochloride)



	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥40000	64400
Tailing factor (Donepezil)	≤1.5	0.99
Relative standard deviation of the peak area (n=5) (Donepezil)	≤2.0 %	0.47 %

(B) Sample solution\*  
(1.0 mg/mL Donepezil hydrochloride)



Column : YMC-Triart C18 (5 μm, 12 nm)  
250 X 4.6 mm I.D.

Eluent : A) 0.1% phosphoric acid in water, adjust pH 6.5 with triethylamine  
B) acetonitrile  
25-60%B (0-10 min), 60%B (10-40 min), 60-25%B (40-41 min), 25%B (41-50 min)

Flow rate : 1.5 mL/min

Temperature : 50°C

Detection : UV at 286 nm

Injection : 20 μL

(The United States Pharmacopeia 37th; Organic impurities, Procedure 2)

\* All standard and sample solutions were prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.

ドネペジル塩酸塩錠（米国薬局方記載条件）

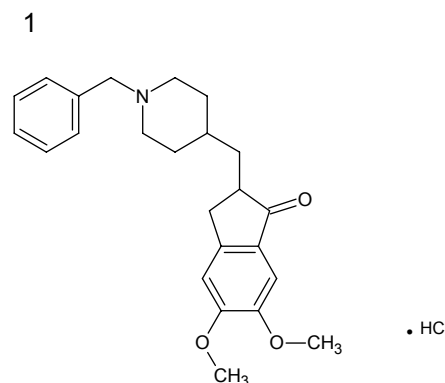
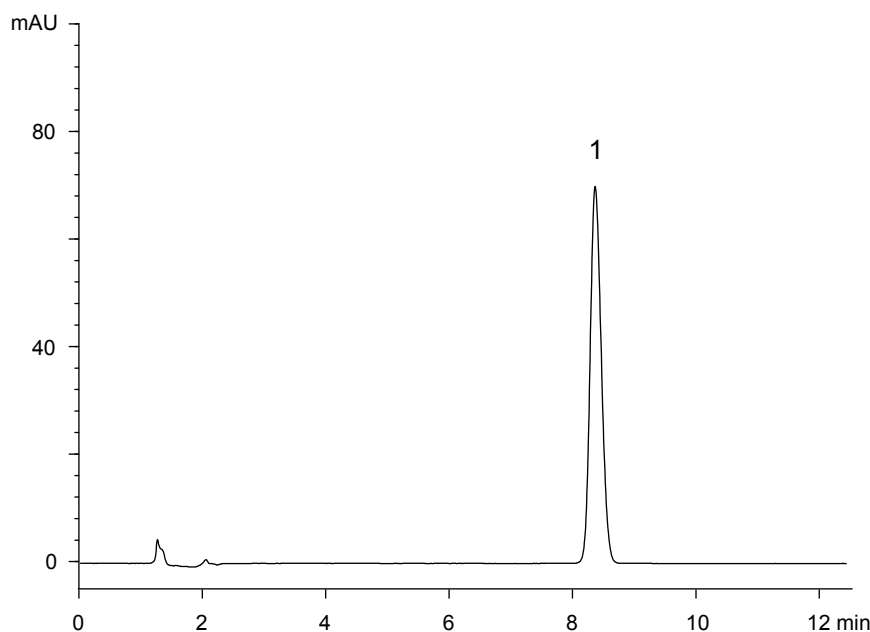
Donepezil hydrochloride Tablets (The United States Pharmacopeia)

F131227C

Standard solution\*

(10 µg/mL Donepezil hydrochloride)

	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 5000	10300
Tailing factor (Donepezil)	≤ 1.5	1.18
Relative standard deviation of the peak area (n=6) (Donepezil)	≤ 2.0 %	0.13 %



Donepezil hydrochloride

Column : YMC-Triart C18 (5 µm, 12 nm)  
150 X 4.6 mm I.D.  
Eluent : acetonitrile/water/perchloric acid (350/650/1)  
Flow rate : 1.0 mL/min  
Temperature : 35°C  
Detection : UV at 271 nm  
Injection : 50 µL  
(The United States Pharmacopeia 37th; Performance tests)

\* Standard solution was prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.